DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Ms Dalia Givony
Regulatory Affairs Manager
Oridion Medical 1987 Limited
7 Hamarpe Street
Har Hotzvim Industrial Park
Jerusalem, Israel 91450

Re: K123690
Trade/Device Name: Capnostream® 20p with HiFi CO2 Monitoring
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: June 15, 2014
Received: June 17, 2014

Dear Ms. Givony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Capnostream®20p with HiFi CO2 monitoring

(This document is not confidential)

August 28, 2013

510(k) Number (if known) K123690

Device Name: Capnostream®20p with HiFi CO2 monitoring

Intended Use/ Indication for Use

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

Capnostream®20p is to be operated by qualified healthcare personnel only. The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

The Capnostream20p HiFi mode provides a measurement of expired carbon dioxide and detects spontaneous breaths for infant/neonatal patients ventilated using high frequency oscillatory ventilation (HFOV).

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Oridion Medical 1987 Ltd.

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510(k) SUMMARY

This summary is being submitted in accordance with the requirements of 21 CFR 807.92

(*This section is not confidential*)

DATE THIS SUMMARY WAS PREPARED

July 31, 2014

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

Oridion Medical 1987 Ltd

7 HaMarpe Street, Har Hotzvim Industrial Park,

Jerusalem, 91450, Israel

ESTABLISHMENT REGISTRATION NUMBER

8044004

CONTACT PERSON:

Dalia Givony, Director of Regulatory Affairs

Oridion Medical 1987 Ltd

Har Hotzvim Science Based Industrial Park

POB 45025

91450 Jerusalem, Israel

Telephone: +972-2-589 9115

FAX: +972-2-586-6680

DEVICE INFORMATION

Trade Name: Capnostream20p with HiFi CO2 monitoring
Common Name: Two Parameter Bedside Monitor
Classification Name: Capnograph/Pulse Oximeter/Ventilatory Effort Recorder
Regulation Number:
21 CFR 868.1400, Carbon dioxide analyzer, (product code CCK)
Secondary product codes: DQA and MNR.

PREDICATE DEVICE

Capnostream20p with HiFi CO2 monitoring is substantially equivalent to the following commercially available devices:

MANUFACTURER DEVICE 510(k) No. Clearance Date

Oridion 1987 Medical Ltd Capnostream20p with Smart A/hr &ODI
K112368 July 19, 2012

DEVICE DESCRIPTION

The Capnostream20p bedside monitor is a two parameter monitor consisting of a microMediCO2 capnography module and a pulse oximetry module implemented in a host device. The host device displays parameters received from the respective modules and generates alarms when preset alarm thresholds are crossed.
The HiFi capnography software feature, presented in this submission, is intended to enable measurement of airway CO2 for infant/neonatal patients during high frequency oscillatory ventilation (HFOV) and detects spontaneous breaths for infant/neonatal patients ventilated using high frequency oscillatory ventilation (HFOV).

INTENDED USE

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous noninvasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.
Capnostream®20p is to be operated by qualified healthcare personnel only.

The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.
The Capnostream20p HiFi mode provides a measurement of expired carbon dioxide and detects spontaneous breaths for infant/neonatal patients ventilated using high frequency oscillatory ventilation (HFOV).

COMPARISON TO PREDICATE DEVICE

The Capnostream20p with HiFi CO2 monitoring is substantially equivalent to the predicate Capnostream20p with Smart A/hr ODI™.

Attribute	**Predicate Device: Capnostream20p with Smart A/hr ODI™ (K112368)**	**Capnostream 20p with HiFi CO2 monitoring**
Classification	II	Same
Product Code & Regulation number	868.1400, Carbon Dioxide Analyzer (Classification CCK) 870.2700 Pulse Oximeter (Classification DQA) 868.2375 Ventilatory Effort Recorder (Classification MNR)	Same
Intended use	The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments. The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon	Same. In addition: The Capnostream20p HiFi mode provides a measurement of expired carbon dioxide and detects spontaneous breaths for infant/neonatal patients ventilated using high frequency oscillatory ventilation (HFOV).

	dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.	
Target population	It is intended for use with neonatal, pediatric, and adult patients. The Smart A/hr and ODI indication for use is for adult patients aged 22 and higher only.	Identical target population for monitoring. In addition HiFi mode is intended for infants and neonates only
Design	Equivalent to the Capnostream20 described in K094012	same
Performance Standards	ISO 21647 ISO 9919	same
Safety Standards	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 ISO 14971 EN 980	same

PERFORMANCE TESTING

The Capnostream20p with HiFi is substantially equivalent to the predicate Capnostream20p with A/hr and ODI.

The new device meets the safety and performance standards met by the predicate device.

Software testing was performed to validate the performance of the new monitor and its substantial equivalence to the predicate device. The functional features and the intended use of Capnostream20p with HiFi are substantially equivalent to the predicate device.

Performance testing conducted on a lung simulator system demonstrated the accuracy of the CO2 measurements in HFOV mode up to a rate of 900 BPM (breaths per minute) (15 Hz) for both passive (ventilator driven) and spontaneous breaths. The testing was conducted for a CO2 range of 16mmHg to 76 mmHg and at spontaneous respiratory rates of 30, 45, and 60 BPM.

A hazard analysis was carried out on the Capnostream host monitor displaying the HiFi values. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the system.

CONCLUSION

The Capnostream20p with the HiFi software feature does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. The minor differences between the Capnostream20p with HiFi and its predicate device raise no issue of safety and effectiveness.

Therefore, the device is substantially equivalent to the predicate devices with respect to safety, effectiveness, and intended use.